

REGIONAL EYE INSTITUTE

THOMAS J. PANGIA, M.D.

EMANUEL NEWMARK, M.D., F.A.C.S.

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December 8, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: 21 CFR Parts 210, 211, 820, 1271
Corneal Donor Tissue

To Whom It May Concern:

I am an ophthalmologist who has successfully restored the sight of Palm Beach County Florida citizens with corneal blindness over the past twenty-five years. No patient in my practice has contracted a blood-borne disease. One hundred percent of my transplanted corneas came from the Florida Lions Eye Bank in Miami. I am opposed to the proposed FDA legislation requiring donor medical history interviews for corneal donors taken under state law by medical examiners. This legislation would require unnecessary and time-consuming screening. The time it would take to locate and interview the next of kin would reduce the length of time a cornea is viable for transplant and sometimes it is virtually impossible to locate next of kin at all in a timely manner. Thereby, reducing the supply of transplantable corneas which is already at short supply and would extend the suffering of thousands of Floridians with impaired vision.

In my professional opinion, the additional screening would not ensure that the corneal tissue did not come from a donor having a communicable disease because frequently the next of kin or others most often have incomplete knowledge of the donors past medical, sexual or social history. Also patients with Creutzfeldt Jakob disease (CJD) in the latent stage would not exhibit any symptoms. Until there is a proven blood test to detect CJD, the FDA cannot ensure that any donor does not harbor the disease simply by requiring a donor medical history interview. The Florida Lions Eye Bank has supplied 28,000 corneas totally free of charge from July 1977 to July 1999. During this time, there has never been any evidence of transmission of CJD to a single recipient.

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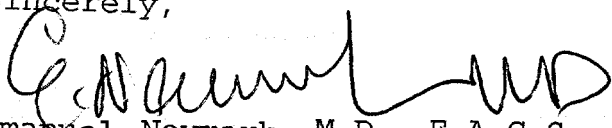
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This legislation must seriously be reassessed, as it will have numerous negative affects on the publics well-being. In fact, the Florida Lions Eye Bank will be forced into charging for their services, thus costing Medicare 1 million dollars each year. More importantly, the eye bank will not be able to serve hundreds of corneally blind patients each year.

I implore you to eliminate the medical history interviews from this proposed regulation.

Sincerely,



Emanuel Newmark, M.D., F.A.C.S.
Clinical Professor of Ophthalmology on the Volunteer Faculty of the
Bascom Palmer Eye Institute University of Miami School of Medicine
Past President of the Florida Society of Ophthalmology
EN/tti/mb

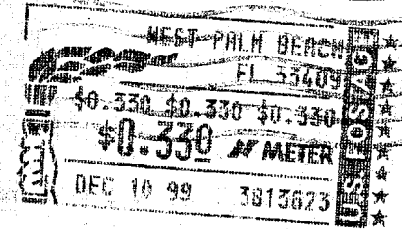
cc: U.S. Senator Bob Graham
U.S. Senator Connie Mack
Representative Mark Foley
Representative Robert Wexler
Representative E. Clay Shaw
Representative Alcee L. Hastings



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